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Title:

Body-worn sensors in Parkinson's disease: evaluating their acceptability to patients

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Parkinson's disease. Body-worn sensors. Home-monitoring.

Running Title:

Acceptability of body-worn sensors in Parkinson's Disease

Abstract

Background:

Remote monitoring of symptoms in Parkinson's Disease (PD) using body-worn sensors would assist treatment decisions and evaluation of new treatments. To date, a rigorous, systematic evaluation of the acceptability of body-worn sensors in PD has not been undertaken.

Materials and Methods:

34 participants wore bilateral wrist-worn sensors for four hours in a research facility and then for one week at home. Participants' views on the sensors were captured using a Likert-style questionnaire after each phase. Qualitative data were collected through free-text responses. Differences in responses between phases were assessed for using the Wilcoxon rank-sum test. Content analysis of qualitative data was undertaken. 'Non-wear time' was estimated via analysis of accelerometer data for periods when sensors were stationary.

Results:

After prolonged wearing there was a negative shift in participants' views on the comfort of the sensor; problems with the sensor's strap were highlighted. However, accelerometer data demonstrated high patient concordance with wearing of the sensors. There was no evidence that participants were less likely to wear the sensors in public. Most participants preferred wearing the sensors to completing symptom diaries.

Discussion:

The finding that participants were not less likely to wear the sensors in public provides reassurance regarding the ecological validity of the data captured. The validity of our findings was strengthened by triangulation of data sources, enabling patients to express their agenda and repeated assessment after prolonged wearing.

Conclusions:

Long-term monitoring with wrist-worn sensors is acceptable to this cohort of PD patients. Evaluation of the wearer's experience is critical to the development of remote-monitoring technology.

1 Introduction

The motor symptoms of Parkinson's disease (PD) include tremor, rigidity and bradykinesia. With prolonged levodopa therapy motor complications such as dyskinesia (additional, involuntary movements) may develop(1). The fluctuations seen in PD render quantification of symptoms challenging. Current gold-standard assessment methods include clinical rating scales(2) and patient-completed symptom diaries, both of which are inherently subjective(3-5).

Body-worn accelerometers have shown great promise as an objective measure of PD symptoms. Accurate detection of tremor(6), bradykinesia(7) and dyskinesia(8) has previously been demonstrated and accelerometers have been employed for prolonged periods of remote symptom monitoring(9). Remote monitoring technology (RMT) of patients' symptoms may enable more informed treatment decisions to be made and the field has been identified as a key research area for the PD community(10). These methods may also yield data for use as an outcome measure for evaluation of new treatments(11). It is recognised that adoption of RMT is dependent on perceptions of the user(12), yet a recent review article highlighting the growing interest of such technology in PD made no reference to any work evaluating the acceptability of such sensors to the wearers(13).

No previous work has formally evaluated whether participants are truly concordant with the wearing of such sensors. Establishing the acceptability of long-term use of body-worn sensors in the home is therefore essential if RMT is to be successfully implemented. We therefore aimed to evaluate the acceptability of wrist-worn sensors in a PD population following assessment after both brief, and prolonged, periods of wearing.

2 Materials and Methods

Ethical approval:

A favourable ethical opinion was provided by County Durham and Tees valley Research Ethics Committee.

Subjects and recruitment:

34 subjects were recruited; all of whom provided informed written consent. This study forms part of research exploring the use of accelerometers to assess upper limb motor symptoms in PD, the analysis of which is on-going. Patients from the Northumbria PD service who fulfilled the following inclusion criteria were recruited: aged >18years, diagnosis of idiopathic PD (United Kingdom Brain Bank Criteria(14)), Hoehn and Yahr(15) stages I-IV, not significantly cognitively impaired (Mini-Mental State Examination(16) of >24) and taking immediate-release levodopa medication. All participants provided informed consent for involvement.

Body-worn sensor:

The sensor (Axivity AX-3)(17) is a waterproof tri-axial accelerometer, which was attached by an adjustable Velcro strap (overall weight 35g). It allows continuous sensing for up to 12 days without the need for recharging. Participants wore a sensor on each wrist (Figure 1) in two different study phases.

Phase 1: Participants attended Newcastle University's Clinical Ageing Research Unit (CARU) and wore the sensors continuously for approximately four hours whilst undergoing clinical assessments.

Phase 2: Participants wore the sensors continuously at home with no clinician input for one week, whilst also completing symptom diaries. Participants were briefed to wear the sensors continuously and to go about their daily activities as normal, but were advised to discontinue wearing them should they become burdensome. Despite the sensors being waterproof, participants were invited to remove the sensors during washing/bathing if they preferred to do so.

Outcome measures:

A questionnaire was developed to capture participants' opinions regarding the sensors. The questionnaire was piloted on a volunteer participant to ensure clarity and readability, and adapted in response to feedback. The questionnaire included nine items (Table 1) and for each item participants indicated their level of agreement on a symmetrical five-point Likert scale. The questionnaire also included a space for participants to provide free-text feedback about the sensors. The same questionnaire was administered on completion of both study phases and was returned to researchers in a pre-paid envelope.

The amount of time that the sensors were not worn during the home monitoring period was estimated by analysis of accelerometer data. Data were examined for minute-long periods for which no orientation change of the sensor was seen. If 10 or more such minutes occurred consecutively, then the full period was classified as time when the sensor was not being worn. To avoid inadvertent

classification of sleep as periods where sensors were not worn, analysis of accelerometer data was restricted to waking hours (defined as 0800 – 2200).

Data analysis:

IBM-SPSS software was used to collate responses and to produce descriptive statistics. Likert response categories were treated as ordinal data, since the intervals between categories cannot be assumed to be of equal magnitude. Significant differences between participants' phase one and two responses were assessed by using the Wilcoxon rank-sum test. Content analysis of free text responses was undertaken. All free-text responses provided were transcribed verbatim. A coding framework was developed to describe the content of the responses (by JF). Comments were categorised by over-arching theme, sentiment (positive or negative) and by study phase (CARU or home). An experienced qualitative researcher (KG), who had no prior involvement with this project, also performed content analysis. The second researcher received transcripts of the free-text comments but was blinded to the content analysis performed by the first researcher. Thereafter, both researchers met to compare analyses and to explore alternate interpretations/coding strategies, a process recognised as improving rigour in content analysis(18). Consensus opinion was reached on the most appropriate content analysis themes from the data captured.

3 Results

Questionnaire: Quantitative data

A total of 34 participants completed the questionnaire after both study phases. The mean age of the study cohort was 69 years (range: 50-86 years) and the average duration of PD was 10 years (range: 2-26 years). Mean MMSE score was 28.6 (range: 26-30). All participants wore the sensors for the duration of phase one; 32 did so for the entirety of phase two. Two patients did not complete phase two: one withdrew after five days (unwell) and one after four days (discomfort wearing sensor); however both participants completed the phase two questionnaire.

608 (99.3%) of a possible 612 responses to the questionnaire items from both phases were completed, with only four invalid responses (three blank, one dual-selection). The frequency of responses to items for each phase are presented in Table 1 below.

Only one participant reported a preference for keeping a symptom diary as opposed to wearing the sensors; this was the participant who withdrew due to sensor discomfort. After completion of phase two, 32/34 (94.1%) participants agreed that they were willing to wear the sensors at home and 29/34 (85.3%) participants agreed that they were willing to wear the sensors in public.

Analysis of participants' responses between study phases revealed a statistically significant ($p<0.05$) change (towards less agreement) in the responses to items one [the sensor looks like it is well made], two [the sensor is comfortable to wear] and five [I would be happy to wear the sensor around the house]. Table 2 displays the magnitude and frequency of change for these three items. On further examination it was evident that the majority of participants showed no change in their responses. For participants whose responses declined in agreement it is evident that the majority did so only by one category, with more pronounced swings in opinion (change ≥2 categories) being rare. A change in opinion of ≥2 categories was only expressed by 2/34 (5.9%) of participants to Item 1, 3/34 (8.8%%) to Item 2 and 2/34 (5.9%) to Item 5). There was no significant difference between the study phases for the responses to the remaining five items considered for both phases of the study.

For items 1, 2 and 5, further analysis was undertaken following contraction of the 5-point Likert scale into a 3-point scale: the responses strongly agree and agree were combined to 'agreement'; strongly disagree and disagree to 'disagreement'; neither agree nor disagree remained unchanged. Analysis using the 3-point scale found no statistically significant change in participants' responses between study phases for items one and five ($p=0.180$ and 0.414 respectively). A statistically significant decrease (towards less agreement) in the responses to item two was evident ($p=0.023$)

Questionnaire: Qualitative data

13 participants (38.2%) provided free-text feedback in the post-CARU questionnaire; 18 (52.9%) did so in the questionnaire completed after the home monitoring period. In total, 25 different participants (73.5%) provided free-text feedback on at least one occasion during the study.

Content analysis, performed as described above, revealed three over-arching themes that are presented below: 'Appearance (Table 3), 'Useability' (Table 4) and 'Comfort' (Table 5). 'Appearance' was sub-divided into 'Physical properties' and 'Wearing in public'. Both 'Useability' and 'Comfort' were sub-divided according to sentiment (positive or negative).

Accelerometer data

The mean duration of 'non-wear time' (time during home monitoring waking hours where the sensors were not worn) was 228.2 minutes (SD = 385.3), equivalent to 32.6 minutes per day. The large standard deviation value is in part explained by one participant who represents a clear outlier. This participant discontinued home monitoring after 4 days citing sensor discomfort and wore the sensors for only 40.3% of home monitoring waking hours. When this outlier was excluded, the mean duration of "non-wear" time was 159.7 minutes (SD = 150.9); equivalent to 22.8 minutes per day (2.72% of waking hours).

4 Discussion

This is the first study to our knowledge to carry out a thorough, detailed evaluation of the acceptability of body-worn sensors in PD. Our research suggests that long-term monitoring with body-worn sensors is acceptable to PD patients – a critical finding, since patient non-concordance with the wearing of a sensor renders even the most sensitive and accurate device virtually useless. Strengths of the work are the triangulation of data from multiple sources to reinforce the validity of our findings, and the consideration of acceptability after both a short and a prolonged period of wearing.

After prolonged wearing participants were less likely to agree that the sensors were comfortable to wear. The mixed methods approach we adopted in this work enabled us to triangulate data and to obtain more detailed insight into participants' experiences of wearing the sensors, since participants were provided with an opportunity to voice their agenda(19). Qualitative data revealed that the main source of sensor discomfort related to the strap. Furthermore, some participants reported problems with ill-fitting straps that resulted in relative motion between the sensor and the body – the resulting extraneous signal artefact may have adversely affected the quality of data captured(20). As a consequence of these findings the strap material, and the method for adjusting the sizing of it, were modified for the latest iteration of the sensor.

Previous research in PD has invariably failed to consider the views of the wearer; Van Someren et al.(21), for example, suggested that wearing a wrist-worn sensor for several weeks would be "no more uncomfortable than wearing a wrist-watch". This is a gross over-simplification and fails to appreciate the psychology associated with the wearing of a medical device.

Despite a decline in patients' views on sensor comfort and their willingness to wear them at home, this did not translate into patients not wearing the sensors, since concordance, as evidenced by the accelerometer-derived wear-time data, was high. On average (excluding an outlier) participants only removed the sensors for approximately 22 minutes per day - participants were invited to remove the sensors during washing/bathing and this period of non-wear time may represent such activities. Lehoux(22) suggested that user-acceptance may also depend on the context in which a sensor is worn, with patients often more self-conscious outside their 'private sphere'. Social embarrassment and the feeling that wearing such a product marked a person as 'old', has been highlighted as a major factor affecting acceptability of body-worn sensors(23). Our findings suggest that long-term monitoring with body-worn sensors is acceptable to PD patients and that the vast majority of participants were willing to wear the sensor both at home and in public, a critical component of ensuring ecological validity of the recorded data.

The only detailed previous work on sensor acceptability in PD(24) showed, in contrast to our findings, a large disparity between participants' willingness to wear sensors at home and in public (Yes: 94% and 55% respectively). If the wearing of a sensor results in modification of the wearer's behaviour, then the ecological validity of the data collected is limited. Critically, Giuffrida et al.(24) polled participants' views in the presence of researchers, in a research facility, and did so after participants had only worn the sensors for a short period. It is possible that these factors may have introduced bias, resulting in false reassurance about the sensors' acceptability. It is recognised that a

degree of obtrusiveness is inevitable with even the most well designed sensor and this may be magnified by more prolonged monitoring periods(25). In our study, polling views after the period of prolonged monitoring did not reveal marked deterioration in the wearability of the sensor, as might be expected if the sensor was not user-friendly(25).

It is well recognised that patient concordance with home diaries, the current gold standard for home monitoring in PD, can be poor, and that entries are often not made contemporaneously(26). Our work revealed that participants overwhelmingly preferred wearing the sensor to completing a diary. Cognitive impairment is common in PD(27) and may impact on a person's ability to accurately complete a home diary; consequently, such patients are frequently under-represented in clinical trials. Body-worn sensors may in future, enable remote monitoring of patients who are unable to maintain symptom diaries. It is however acknowledged that the acceptability of sensors in this group is not yet established, since cognitively impaired patients were not involved in this work.

A potential limitation of our work is that the study population may not be truly reflective of the wider PD population. Those engaging with such a research project may be more willing to wear such a sensor. We believe that this effect is likely to be minimal since the study inclusion criteria were broad, thus reflecting a spectrum of disease, and the study protocol was not particularly arduous. 10 patients did decline participation in the study; none cited unwillingness to wear the sensors as their reason for non-participation. Secondly, this research used only wrist-worn sensors and thus our conclusions may not be applicable to sensors worn elsewhere on the body; less conspicuous sensor placement may further improve acceptability.

This research has highlighted the central importance of patient acceptability to home-monitoring systems. A recent United Kingdom Department of Health mandate(28) targeted increased availability of home-monitoring of chronic long-term health conditions by 2017. In this respect, prolonged monitoring requires a sensor to be as un-obtrusive and as wearable as possible to avoid declining patient concordance during the monitoring period(25). Our work has demonstrated the acceptability of the sensors employed and has highlighted the need to consider patients' views when such systems are trialled. Further research might explore the acceptability of sensors worn in other body areas or modification of the wrist-worn sensor to include a functioning watch-face, which may improve acceptability further.

5 Conclusions

- The wearer's perspective must be considered when body-worn technology is being developed and evaluated.
- Bilateral wrist worn sensors were acceptable to our population of patients with Parkinson's disease, even after a period of prolonged wearing.
- There was no evidence that participants were less likely to wear the sensors in public; a key finding to support the ecological validity of the data captured.
- A mixed methods approach allowed triangulation of data relating to the patient experience and has directly informed further development of the sensor.

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No conflicts of interest exist for any of the contributing authors

This study underwent full ethical review and was given a favourable ethical opinion by County Durham and Tees valley Research Ethics Committee. It was therefore performed in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki and its later amendments.

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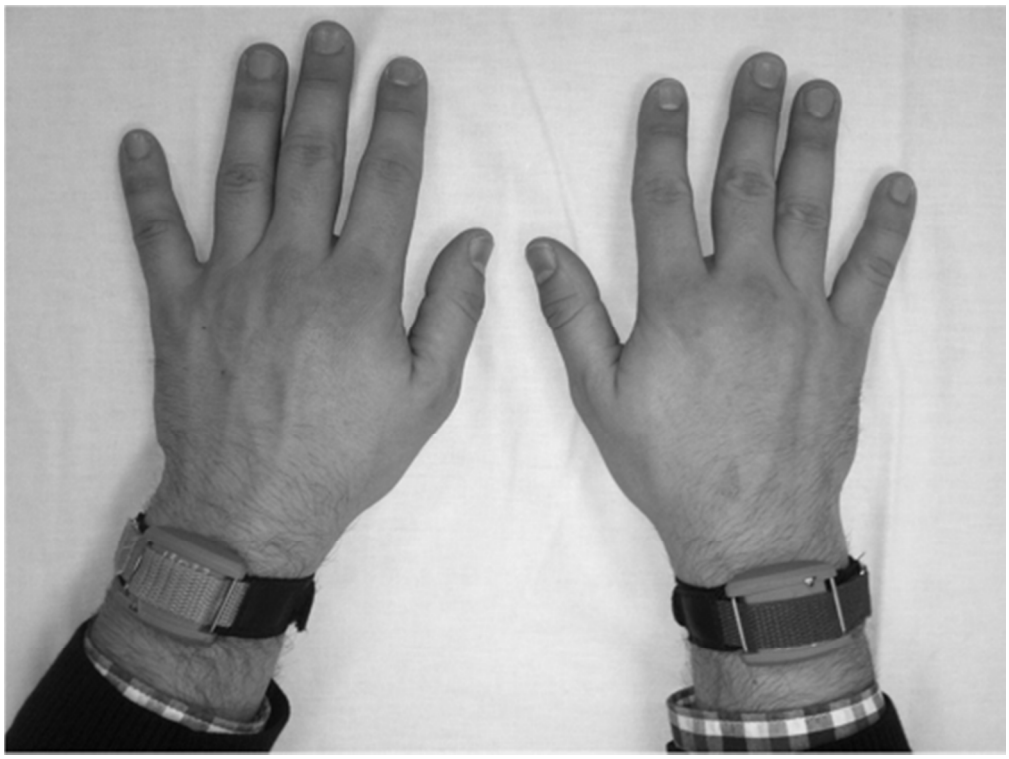

Bilateral wrist-worn sensors
85x64mm (150 x 150 DPI)

Table 1: Frequency of responses to questionnaire after CARU and Home phases

Item		Frequency of response				
		Strongly Agree	Agree	Neither Agree Nor Disagree	Disagree	Strongly Disagree
1*) The sensor looks like it is well made	CARU	13	21	0	0	0
	HOME	4	28	1	0	1
2*) The sensor is comfortable to wear	CARU	12	21	1	0	0
	HOME	3	25	3	3	0
3) The sensor feels heavy on my arm	CARU	0	0	3	19	12
	HOME	0	1	4	15	14
4) Performing the assessments was made more difficult by wearing the sensor	CARU	0	0	0	17	16
	HOME[$]					
5*) I would be happy to wear the sensor around the house	CARU	15	18	1	0	0
	HOME	9	23	1	1	0
6) I would rather keep a regular diary of my symptoms for a week than wear the sensor for a week	CARU	0	0	5	18	11
	HOME	0	1	6	18	9
7) If the sensor was incorporated into a working wrist-watch I would be more likely to wear it	CARU	4	16	5	8	1
	HOME	5	13	7	6	2
8) The sensor is easy to take on and off	CARU	8	19	5	1	0
	HOME	5	24	2	2	0
9) I would be happy to wear the sensor in public	CARU	10	23	1	0	0
	HOME	7	22	3	2	0

* statistically significant difference in responses CARU - home ($p<0.05$)
[$] question excluded as not relevance to home phase of study

Table 1: Scale and frequency of the change in response for items where a significant difference was detected

	Change in response	Frequency		
		The sensor looks like it is well made (Item 1)	The sensor is comfortable to wear (Item 2)	I would be happy to wear the sensor around the house (Item 5)
More positive ->	+4	0	0	0
	+3	0	0	0
	+2	0	0	0
	+1	0	1	2
No change	0	24	19	24
<- More negative	-1	8	11	6
	-2	1	2	2
	-3	1	1	0
	-4	0	0	0

Table 3: Content Analysis: Appearance

APPEARANCE			
Patient ID	**Phase**	**Comment**	
GHRS	Home	"Would prefer it to be a little smaller and with watch face as keep thinking it was a watch I was wearing"	**Physical properties**
UVTR	Home	"The only problem was that I kept looking to find the time!"	
MZGE	Home	"Wore it for a week, did not cover it up"	**Wearing in public**
GHRS	Home	"I would not like to wear in warm summer months as more noticeable to people and questions"	
GHRS	CARU	"Happy to wear (in public) but would not like members of public questioning what it is for as illness is private"	

Table 4: Content Analysis: Useability

USEABILITY			
Patient ID	**Phase**	**Comment**	
MXRL	Home	"I had expected it to interfere with my everyday life but that did not happen"	**Positive**
WDSJ	CARU	"Someone will do [put on/off] for me"	
MUCL	CARU	"The sensor was very easy to have on"	
MUCL	Home	"The sensor I found easy to wear"	
ATYY	Home	"The sensor is easy to take on and off"	
PQEP	Home	"Because I have small wrists the sensors were swinging around and it was difficult to keep them in the upright position. After a couple of hours I used some surgical tape to stick it down where the strap fastens underneath - they are in the same position after one week including daily showers	**Negative**
GHRS	Home	"Found it restricts you wearing tight sleeves on clothes"	
MUCL	Home	"Felt a little nervous having a shower"	
WDSJ	Home	"The left, blue sensor did not always stay securely in position and so needed occasional readjustment"	
FRMQ	Home	"I removed them whilst having a bath/shower because they became soggy"	
FRMQ	Home	"For someone with a tremor they are a little awkward"	
BRCN	Home	"Maybe stronger pins in the sensor would help, one came out"	
NRWL	Home	"Sensor a little awkward to fasten the strap… when feeling off"	

Table 5: Content Analysis: Comfort

COMFORT			
Patient ID	**Phase**	**Comment**	
CGLT	CARU	"It feels no different to wearing a watch"	**Positive**
QXLL	CARU	"Feels comfortable, don't mind having it on"	
MXRL	Home	"Found the sensor quite comfortable to wear"	
QXZV	Home	"Very comfortable to wear - just like wearing a watch"	
MZGE	Home	"No problem. Forgot it was there"	
QXLL	Home	"No problems with sensor, almost forgot it was on"	
UGNK	CARU	"Strap would be more comfortable if leather"	**Negative**
LAPC	Home	"Velcro slightly uncomfortable"	
FRMQ	Home	"The sensor is slightly scratchy especially when wearing a watch as well"	
ATYY	Home	"It is always on your skin, also, when it gets wet it is very uncomfortable to wear generally and I don't like it very much"	
GHRS	Home	"Comfortable to wear, however, after a week of constant wear feeling a little irritating"	
JKVJ	Home	"If strap were more comfortable would make wearing very easy"	